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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,979	01/08/2004	Martin Brady	SCHWP0211USA	6449

46140 7590 11/05/2009

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EXAMINER	
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ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
11/05/2009	PAPER

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/753,979
Filing Date: January 08, 2004
Appellant(s): BRADY ET AL.

Don W. Bulson
For Appellant

EXAMINER'S ANSWER

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

2006/0084943	ROSENMAN ET AL.	04-2006
6,743,218	MAGINOT ET AL.	06-2004
5,603,703	ELSBERRY ET AL.	02-1997
5,342,383	THOMAS	08-1994

5,137,515 HOGAN 08-1992

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 6, 8, 11, 12 and 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry et al. (US Patent No. 5,603,703) in view of Thomas (US Patent No. 5,342,383) and further in view of Rosenman et al. (US 2006/0084943). Elsberry discloses a system comprising a hollow rigid tube (Fig. 1, 16; col. 3, lines 18-19), including a proximal end (above element 12, near 14) and a distal end (near 20) and a lumen extending there between, wherein the hollow tube is shaped and sized to

permit insertion into a lumen of a flexible tubular infusion catheter (element 18; col. 1, lines 9-13; col. 3, lines 56-59; col. 5, lines 6-18 all disclose that while the title of the invention is directed towards aspiration, the invention can be used for infusion, and thus is also an infusion catheter), and wherein the hollow tube is stiffer than the infusion catheter (col. 4, lines 29-31 disclose that a rigid stylet is used to add rigidity to the stylet/catheter combination, which means that the stylet is inherently stiffer than the catheter, otherwise a rigid stylet wouldn't be needed) such that the hollow tube acts as a stylet for guiding the catheter through tissue to a target location.

Elsberry further discloses that the lumen of the hollow tube is filled with a fluid, and in which the proximal end of the hollow tube is configured to be closed to retain the fluid within the lumen of the hollow tube (col. 4, lines 56-66). Elsberry also discloses that a fluid reservoir is coupled to the proximal end of the hollow tube (col. 3, lines 42-44). Elsberry also discloses that the hollow tube and the fluid reservoir are sized to hold enough fluid to fill the lumen of the infusion catheter after withdrawal of the hollow tube from the lumen of the infusion catheter (col. 3, lines 56-66). Elsberry further discloses a flexible tubular infusion catheter (18) including a proximal end (near 12) and a distal end (near 20) and a lumen extending there between, the lumen of the infusion catheter sized and shaped to permit insertion of the hollow tube therein (see Fig. 1). Elsberry further discloses that the proximal end of the infusion catheter sealingly engages around the hollow tube when a portion of the hollow tube is located within the lumen of the infusion catheter (22 forms a seal around 16, alternatively see Fig. 4). Elsberry also discloses that the lumen of the catheter includes a diameter having at least two different

values at different locations along the lumen of the catheter (Fig. 3 discloses that the catheter, here 26, has tow different diameters, a larger diameter near the holes (28) and a smaller diameter near the tip). Elsberry also discloses means for temporarily sealing the proximal end (12) of the hollow tube to retain fluid within the hollow tube.

Elsberry further discloses a method comprising loading a hollow-tube stylet with fluid (col. 8, line 64); inserting the stylet into a lumen of a flexible infusion catheter to provide enough stiffening to the catheter to guide the catheter through living tissue toward a target (col. 8, lines 51-52 and lines 65-67); directing the stylet and the catheter through tissue to the target (col. 4, lines 30-37; please note that in each claim, the phrase "as the hollow rigid tube is tunneled through tissue" is functional language, and the device disclosed by Elsberry if capable of performing the function of tunneling, especially as it is well known in the art that a catheter that first enters the vasculature must first be tunneled through the skin, fat and tunnel into the vessel in order to enter the vasculature); and withdrawing the stylet from the catheter, in which the withdrawing includes releasing the fluid from the stylet into the lumen of the catheter to avoid air form occupying the lumen of the catheter upon withdrawal of the stylet (col. 9, lines 1-2 and claim 35). Elsberry further discloses temporarily closing a proximal end of the stylet, after loading the stylet with fluid, to assist in retaining the loaded fluid within the stylet (col. 4, lines 65-67). Elsberry further discloses opening the proximal end of the stylet after inserting the stylet into the lumen of the catheter and before withdrawing the stylet, to release fluid from the stylet into the lumen of the catheter and further including

infusing a fluid agent through the catheter after withdrawing the stylet (claims 31 and 35).

Elsberry, however, does not disclose that the hollow rigid tube (stylet) has a remotely detectable locator positioned on the tube allowing the stylet to be tracked by a positioning system for proper positioning of the catheter within the patient's body. Thomas, however, discloses a stylet having a radiopaque material at the tip allowing the stylet to be tracked and viewed radiographically when positioned within the patient's body, thus allowing the physician to properly position the catheter which surrounds the stylet (abstract; col. 3, lines 10-18 in Thomas disclose that the radiopaque material is preferably barium sulfate and that this material is visualized radiographically in tracking the location of the device). The radiopaque material at the tip therefore is equivalent to the remotely detectable locator, as this is detected remotely (its position is detected and viewed on a monitor by the physician, which is obviously remote from the interior of the body in which the stylet is located). The radiographic system used by the physician and medical personnel to view the stylet is equivalent to the positioning system and image guided surgical workstation claimed, as this is a system used/viewed in surgery for positioning the stylet and catheter. Furthermore, the progress of the locator can be tracked and displayed by taking multiple radiographic images during it's travel through the body. While the examiner believes that it is obvious that a form of radiography used to track the device would also include displaying the resulting images on a monitor as part of an image guided workstation, such as in fluoroscopy, the Rosenman reference explicitly makes this connection obvious. Rosenman discloses a similar medical device

that is tunneled through the body and includes a radiopaque marker on the device made from barium sulfate (paragraph [0042]; the same as the radiopaque marker used by Thomas), and further discloses that the device is tracked radiographically by fluoroscopy (also in paragraph [0042]. It is well known to one of ordinary skill in the art at the fluoroscopy involves imaging the patient and the device within the patient and displaying the resulting images on the monitor of a surgical guided work station). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry with the remotely detectable radiopaque locator, as taught by Thomas and further supported by Rosenman, especially since Rosenman teaches the exact same type of radiopaque marker for imaging as is used in Thomas (paragraph [0042] in Rosenman), in order to provide a guiding and positioning system to properly and accurately position the catheter and stylet for treatment.

Claims 7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry in view of Thomas, further in view of Rosenman and further in view of Maginot et al. (US Patent No. 6,743,218). Elsberry in view of Thomas and further in view of Rosenman discloses the device substantially as claimed except for a clamp. Maginot, however, discloses a clamp (Fig. 3, 62 and 64) to be used at the proximal end of the catheter to prevent any fluid flow through the catheter system (col. 12, lines 12-18). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry in view of Thomas and further in view of Rosenman

with the clamp as taught by Maginot in order to provide another mechanism in which stop the flow of fluid through the hollow tube.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elsberry in view of Thomas, further in view of Rosenman and further in view of Hogan (US Patent No. 5,137,515). Elsberry in view of Thomas and further in view of Rosenman discloses the device substantially as claimed except for a cap and a plug at the end of the proximal tube. Hogan, however, discloses a cap (Fig. 1, 34) and plug (32) for the ends of a hollow tube (col. 3, lines 3-9). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Elsberry in view of Thomas and further in view of Rosenman with the cap and plug as taught by Hogan in order to provide mechanisms to seal the end of the hollow tube.

(10) Response to Argument

In response to Appellant's arguments against claim 1 and that it would not have been obvious to look to Thomas to cure the deficiency of Elsberry since Elsberry's purpose is to prevent coring of tissue, the examiner would like to point out that Elsberry was used as the primary reference because it had all of the structure claimed by Appellant except for the remotely detectable locator. The examiner brought Thomas in as a secondary reference because it teaches an obturator (equivalent to Appellant's claimed inner rigid tube used for guiding) which is inserted into a catheter and used to

guide a catheter for placement, similar to Applicant's system, and more importantly because it teaches that the obturator has a radiopaque marker (band of radiopaque material) at its tip. The radiopaque material can be visualized radiographically, such as via fluoroscopy, to see where the tip of the obturator is within the patient's body in order to position the obturator and catheter in the correct position (abstract and col. 3, lines 10-18 of Thomas).

Appellant further argues that the combination of Elsberry and Thomas do not teach "real time tracking". The examiner would like to point out, however, that Appellant has not claimed "real time tracking" within the claim language. Appellant is arguing narrower details that what is actually being claimed. Appellant further argues that the claimed "image-guided surgical workstation" is known to one of ordinary skill in the art to be a system that provides real time tracking, however, Appellant's specification does not define the "image-guided surgical workstation" as needing to provide real time tracking. If one looks to Appellant's specification, Appellant only describes the image-guided surgical workstation in paragraphs 2 and 3 of page 6 and the first paragraph of page 7. No where in the specification is the image guided surgical workstation defined as a real time tracking system, and no where in the claims is there any requirement for real time tracking.

Furthermore, it is the examiner's position that even if Appellant had support for real time tracking, the tracking of Thomas' radiopaque marker via fluoroscopy (as Rosenman discloses) could be considered real time tracking. Fluoroscopy involves taking a radiographic image of the marked device in the patient, and then viewing the

image on a screen to ensure that the device is in the correct position. The device can then be moved/adjusted further within the patient and another image can be taken to ensure correct placement, and then the device can be moved further, another image taken, and so on. This may be a bit slower of a process, but it can be considered to be done in real time.

With respect to Appellant's arguments regarding claim 2 and Elsberry's device not being able to hold fluid in the hollow tube, as is claimed, due to Elsberry's backfill hole 24, it is the examiner's position that the valve 12 of Elsberry is closed to retain what fluid is in the tube during insertion of the device. Just as a drinking straw has two open ends, when the straw is in a cup filled with liquid and some liquid is within the straw, when a person places a finger over one open end of the straw and lifts the straw out of the cup of liquid, the liquid that is within the straw does not flow out the open end. The finger over the open end of the straw (equivalent to Elsberry's valve 12) creates a vacuum within the device preventing fluid from exiting the other open hole in the straw (equivalent to Elsberry's hole 24). Therefore when valve 12 is closed, it will retain any fluid that is within the inner hollow tube. Also see Elsberry, col. 4, line 56 through col. 5, line 3.

With respect to Appellant's arguments regarding claim 11 and the previously argued real time tracking, the examiner would again like to point out that "real time tracking" is not present within the claim language, nor does Appellant have such support for this type of tracking within their specification. The examiner's arguments presented regarding claim 1 also apply here.

With respect to Appellant's arguments regarding 16 and the presence of hole 24 in Elsberry, which Appellant argues would allow air to pass between the inner tube and the catheter when the inner tube is withdrawn from the catheter, the examiner would like to point out that Elsberry provides element 22 (sealing means) which allows a portion of the inner tube to seal snugly against the inner surface of the catheter. The examiner would further like to point out that Elsberry discloses that the when the device is filled with fluid prior to insertion in the patient, the device is filled such that it is an air-free column of fluid (col. 4, lines 60-65). Therefore there is no air present within the assembly. Once the assembly is tunneled into the patient, the inner tube is withdrawn from the catheter and the vacuum created between the catheter and the inner tube pulls the fluid from the inner tube so that it empties into the catheter. Since the assembly was filled such that it was "air-free", no air would pass between the two tubes despite the presence of hole 24.

With respect to Appellant's arguments regarding claim 18 and the previously argued real time tracking, the examiner would again like to point out that "real time tracking" is not present within the claim language, nor does Appellant have such support for this type of tracking within their specification. The examiner's arguments presented regarding claim 1 also apply here.

With respect to Appellant's arguments regarding claims 7 and 15 and Maginot only showing a clamp for closing a catheter on itself, it is the examiner's position that Maginot shows a clamp used for clamping tubing closed, and that clamping tubing of various durometers (plastic strengths) is well known in the art and that the addition of the Maginot reference to the rejection is to indicate this point and to show that adding a clamp to Appellant's system does not make Appellant's system novel or non-obvious.

With respect to Appellant's arguments regarding claims 13 and 14 and that Hogan discloses that caps and plugs for tubes are well recognized, but that Appellant's novelty is the system as claimed in claim 1, in addition to a cap or a plug for the system. As presented in arguments for claim 1 above, it is the examiner's position that the combination of Elsberry, Thomas and Rosenman teach the claimed system, and the

addition of the Hogan reference teaches the system with a cap and/or plug as shown in Fig. 1 (elements 32 and 34) in Hogan.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Laura C Schell/

Examiner, Art Unit 3767

Conferees:

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

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